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Attorneys for Defendant Merck & Co., Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DENNIS RINI, as Proposed Administrator of the Estate of EILEEN ANDERSON, Deceased,

Plaintiff,

-against
MERCK & CO., INC., a Domestic Corporation,

Defendant.

Defendant.

Defendant Merck & Co., Inc. ("Merck") answers the Complaint ("Complaint") herein as follows:

RESPONSE TO "STATEMENT OF THE PARTIES"

- 1. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 1, including subparagraphs a and b, of the Complaint, except admits, upon information and belief, that Dennis Rini is a resident of the State of Kansas and that Plaintiff purports to bring a claim for certain damages but denies that there is any legal or factual basis for relief.
- 2. Denies each and every allegation contained in paragraph 2 of the Complaint except admits that Merck is a New Jersey Corporation with its principal place of business

in New Jersey and is authorized to do business in the State of New York and that Merck manufactured, marketed and distributed the prescription medicine Vioxx until its voluntary withdrawal from the worldwide market on September 30, 2004.

3. Denies each and every allegation contained in paragraph 3 of the Complaint.

RESPONSE TO "JURISDICTION AND VENUE"

- 4. Admits the allegations contained in paragraph 4 of the Complaint.
- 5. Admits the allegations contained in paragraph 5 of the Complaint.
- 6. The allegations contained in paragraph 6 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx and that Merck is authorized to do business in New York.
- 7. Denies each and every allegation contained in paragraph 7 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.
- 8. Denies each and every allegation contained in paragraph 8 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx and that Merck is authorized to do business in the State of New York.

RESPONSE TO "STATEMENT OF FACTS"

- 9. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 9 of the Complaint.
- 10. The allegations contained in paragraph 10 of the Compliant are legal conclusions and therefore no responsive pleading is required. Should a response be

deemed required, Merck denies each and every allegation contained in said sentences except admits that there is diversity jurisdiction and that Plaintiff purports to put more than \$75,000 in controversy but denies that there is any legal or factual basis for relief.

- 11. Denies each and every allegation contained in the first sentence of paragraph 11 of the Complaint except admits that Merck is a New Jersey Corporation with its principal place of business in New Jersey. The allegations contained in the second and third sentences of paragraph 11 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said sentences except admits that there is diversity jurisdiction and that Plaintiff purports to put more than \$75,000 in controversy but denies that there is any legal or factual basis for relief.
- 12. Denies each and every allegation contained in paragraph 12 of the Complaint except admits that Vioxx is the brand name for rofecoxib and that Vioxx reduces pain and inflammation and the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2) and that Merck marketed the prescription medicine Vioxx.
 - 13. Denies each and every allegation contained in paragraph 13 of the Complaint. RESPONSE TO "COUNT I – STRICT PRODUCTS LIABILITY"
- 14. With respect to the allegations contained in paragraph 14 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 13 of this Answer with the same force and effect as though set forth here in full.
 - 15. Denies each and every allegation contained in paragraph 15 of the Complaint.

- 16. Denies each and every allegation contained in paragraph 16 of the Complaint.
- 17. Denies each and every allegation contained in paragraph 17 of the Complaint.
- 18. With respect to the allegations contained in paragraph 18 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 17 of this Answer with the same force and effect as though set forth here in full.
 - 19. Denies each and every allegation contained in paragraph 19 of the Complaint.
 - 20. Denies each and every allegation contained in paragraph 20 of the Complaint.
 - 21. Denies each and every allegation contained in paragraph 21 of the Complaint.
 - 22. Denies each and every allegation contained in paragraph 22 of the Complaint.
- 23. With respect to the allegations contained in paragraph 23 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 22 of this Answer with the same force and effect as though set forth here in full.
- 24. Denies each and every allegation contained in paragraph 24 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.
 - 25. Denies each and every allegation contained in paragraph 25 of the Complaint.

RESPONSE TO "COUNT II – FRAUD"

- 26. With respect to the allegations contained in paragraph 26 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 25 of this Answer with the same force and effect as though set forth here in full.
 - 27. Denies each and every allegation contained in paragraph 27 of the Complaint.

RESPONSE TO "COUNT III – NEGLIGENCE"

- 28. With respect to the allegations contained in paragraph 28 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 27 of this Answer with the same force and effect as though set forth here in full.
- 29. Denies each and every allegation contained in the first sentence of paragraph 29 of the Complaint. The allegations contained in the second sentence of paragraph 29 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said sentence. Denies each and every allegation contained in the third and fourth sentences of paragraph 29 of the Complaint.
 - 30. Denies each and every allegation contained in paragraph 30 of the Complaint.
 - 31. Denies each and every allegation contained in paragraph 31 of the Complaint.

RESPONSE TO "COUNT IV - NEGLIGENCE MISREPRESENTATION"

- 32. With respect to the allegations contained in paragraph 32 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 31 of this Answer with the same force and effect as though set forth here in full.
 - 33. Denies each and every allegation contained in paragraph 33 of the Complaint.
- 34. Denies each and every allegation contained in paragraph 34 of the Complaint, including subparagraphs a through f.

RESPONSE TO "COUNT V – EXPRESSED WARRANTY FOR GOODS"

35. With respect to the allegations contained in paragraph 35 of the Complaint,
Merck repeats and re-alleges each and every admission, denial, averment, and statement

contained in paragraphs 1 through 34 of this Answer with the same force and effect as though set forth here in full.

Denies each and every allegation contained in the first, second, third and fifth 36. sentences of paragraph 36 of the Complaint. The allegations contained in the third sentence of paragraph 36 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said sentence.

RESPONSE TO "COUNT VI – IMPLIED WARRANTY"

- 37. With respect to the allegations contained in paragraph 37 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 36 of this Answer with the same force and effect as though set forth here in full.
 - 38. Denies each and every allegation contained in paragraph 38 of the Complaint.
- 39. With respect to the allegations contained in paragraph 39 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 38 of this Answer with the same force and effect as though set forth here in full.
 - 40. Denies each and every allegation contained in paragraph 40 of the Complaint.

RESPONSE TO "COUNT VIII – SURVIVAL ACTION"

- 41. With respect to the allegations contained in paragraph 41 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 40 of this Answer with the same force and effect as though set forth here in full.
 - 42. Denies each and every allegation contained in paragraph 42 of the Complaint.

RESPONSE TO "COUNT IX – WRONGFUL DEATH"

- 43. With respect to the allegations contained in paragraph 43 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 42 of this Answer with the same force and effect as though set forth here in full.
 - 44. Denies each and every allegation contained in paragraph 44 of the Complaint.
 - 45. Denies each and every allegation contained in paragraph 45 of the Complaint.
 - 46. Denies each and every allegation contained in paragraph 46 of the Complaint.

RESPONSE TO "DAMAGES"

47. Denies each and every allegation contained in paragraph 47 of the Complaint.

RESPONSE TO "PUNITIVE DAMAGES"

48. Denies each and every allegation contained in paragraph 48 of the Complaint.

RESPONSE TO "JURY DEMAND"

49. Plaintiff's "Jury Demand" section of the Complaint is not an allegation and therefore no responsive pleading is required.

RESPONSE TO "PRAYER FOR RELIEF"

50. Plaintiff's "Prayer For Relief" section of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation in the "Prayer For Relief" section of Plaintiff's Complaint and denies that Plaintiff is entitled to the relief requested.

AS FOR A FIRST DEFENSE, MERCK ALLEGES:

51. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and statutes of repose and is otherwise untimely.

AS FOR A SECOND **DEFENSE, MERCK ALLEGES:**

52. The Complaint fails to state a claim upon which relief can be granted.

AS FOR A THIRD **DEFENSE, MERCK ALLEGES:**

53. The claims of the Plaintiff may be barred, in whole or in part, from recovery because he has made statements or taken actions that preclude him from asserting claims or constitute a waiver of his claims.

AS FOR A FOURTH **DEFENSE, MERCK ALLEGES:**

The claims of the Plaintiff may be barred, in whole or in part, from recovery 54. because of the res judicata effect of prior judgments.

AS FOR A FIFTH **DEFENSE, MERCK ALLEGES:**

55. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

AS FOR A SIXTH **DEFENSE, MERCK ALLEGES:**

56. If Plaintiff or Plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were cause in whole or in part through the operation of nature or other intervening cause or causes.

AS FOR A SEVENTH **DEFENSE, MERCK ALLEGES:**

57. To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

AS FOR AN EIGHTH **DEFENSE, MERCK ALLEGES:**

58. To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff or Plaintiff's decedent directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

AS FOR A NINTH **DEFENSE, MERCK ALLEGES:**

59. If Plaintiff or Plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff or Plaintiff's decedent knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

AS FOR A TENTH **DEFENSE, MERCK ALLEGES:**

60. If Plaintiff or Plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

AS FOR AN ELEVENTH **DEFENSE, MERCK ALLEGES:**

61. If Plaintiff or Plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's decedent's misuse or abuse of Vioxx.

AS FOR A TWELFTH **DEFENSE, MERCK ALLEGES:**

62. If Plaintiff or Plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's decedent's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

AS FOR A THIRTEENTH **DEFENSE, MERCK ALLEGES:**

To the extent Plaintiff or Plaintiff's decedent settled or will in the future settle 63. with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

AS FOR A FOURTEENTH **DEFENSE, MERCK ALLEGES:**

To the extent Plaintiff is seeking recovery for benefits entitled to be received or 64. actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

AS FOR A FIFTEENTH **DEFENSE, MERCK ALLEGES:**

65. Plaintiff's claims of fraud are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure.

AS FOR A SIXTEENTH DEFENSE, MERCK ALLEGES:

66. Plaintiff's claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

AS FOR A SEVENTEENTH DEFENSE, MERCK ALLEGES:

67. Plaintiff's claims are barred in whole or in part by the First Amendment.

AS FOR A EIGHTEENTH DEFENSE, MERCK ALLEGES:

68. Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

AS FOR A NINETEENTH DEFENSE, MERCK ALLEGES:

69. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

AS FOR A TWENTIETH DEFENSE, MERCK ALLEGES:

70. This case is more appropriately brought in a different venue.

AS FOR A TWENTY-FIRST DEFENSE, MERCK ALLEGES:

71. The claims of Plaintiff may be barred, in whole or in part, from recovery because, in this or other courts, he has brought actions and has received judgments on parts of some or all claims asserted herein.

AS FOR A TWENTY-SECOND **DEFENSE, MERCK ALLEGES:**

72. The claims of Plaintiff may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

AS FOR A TWENTY-THIRD **DEFENSE, MERCK ALLEGES:**

73. The claims of Plaintiff may be barred, in whole or in part, from recovery by release as to his claims.

AS FOR A TWENTY-FOURTH **DEFENSE, MERCK ALLEGES:**

74. The claims of Plaintiff may be barred, in whole and in part, by the doctrine of laches.

AS FOR A TWENTY-FIFTH **DEFENSE, MERCK ALLEGES:**

75. The claims of Plaintiff are barred, in whole or in part, by his failure to mitigate damages.

AS FOR A TWENTY-SIXTH **DEFENSE, MERCK ALLEGES:**

76. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

AS FOR A TWENTY-SEVENTH **DEFENSE, MERCK ALLEGES:**

77. The claims of Plaintiff may be barred, in whole or in part, from recovery, due to spoliation of evidence.

AS FOR A TWENTY-EIGHTH **DEFENSE, MERCK ALLEGES:**

78. The claims of Plaintiff may be barred, in whole or in part, by the governing state laws.

AS FOR A TWENTY-NINTH **DEFENSE, MERCK ALLEGES:**

79. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

AS FOR A THIRTIETH **DEFENSE, MERCK ALLEGES:**

80. Plaintiff has not sustained any injury or damages compensable at law.

AS FOR A THIRTY-FIRST **DEFENSE, MERCK ALLEGES:**

81. To the extent that Plaintiff seeks exemplary or punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

AS FOR A THIRTY-SECOND **DEFENSE, MERCK ALLEGES:**

82. To the extent that Plaintiff seeks exemplary or punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of exemplary or punitive damages is barred.

AS FOR A THIRTY-THIRD **DEFENSE, MERCK ALLEGES:**

83. Plaintiff's demand for exemplary or punitive damages is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

AS FOR A THIRTY-FOURTH **DEFENSE, MERCK ALLEGES:**

84. Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

AS FOR A THIRTY-FIFTH **DEFENSE, MERCK ALLEGES:**

85. Plaintiff's claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

AS FOR A THIRTY-SIXTH **DEFENSE, MERCK ALLEGES:**

86. Plaintiff's claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

AS FOR A THIRTY-SEVENTH **DEFENSE, MERCK ALLEGES:**

87. Plaintiff's claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

AS FOR A THIRTY-EIGHTH **DEFENSE, MERCK ALLEGES:**

88. Plaintiff's claims are barred by the doctrine of contributory negligence.

AS FOR A THIRTY-NINTH **DEFENSE, MERCK ALLEGES:**

89. Plaintiff lacks standing to bring claims.

Inasmuch as the Complaint does not describe the alleged underlying claims with

sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED:

New York, New York

May //, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By:

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